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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,810	03/29/2002	Christopher V W Hogue	571-766	4836

1059 7590 11/03/2005

BERESKIN AND PARR
40 KING STREET WEST
BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,810	HOGUE ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/13/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group III, claims 32-44, in the reply filed on May 11, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is indefinite. Step (a) recites incorporating a biomolecular interaction within a carrier and step (b) recites forming an array of sol-gel derived spots on a support wherein each spot contains a biomolecular interaction. Is the biomolecular interaction in step (a) the same with that in step (b)? If so, what's the spatial relationship of the carrier with respect to the array formed in step (b)? In step (a), the biomolecular interaction is within a carrier but in step (b) it is on a support of an array.

Claim 43, the body of the claim is inconsistent with the preamble. The preamble recites a method...for pre-screening a substance for binding or inhibiting a biomolecular interaction. However, the last step is a step of determination of retention behavior of fluorescence or mass spectrometry.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Charych et al. (US 6,022,748).

Charych teaches a screening assay to observe competitive inhibition of natural binding event of a biomolecular interaction between the target analyte and its natural receptor by using a ligand as a competitive binder (compound that causes inhibition) to the analyte. For example by measuring the colorimetric response to an analyte in the presence of a natural receptor for the analyte. The compositions of Charych also provide means for testing libraries of materials, as the binding desired material can be colorimetrically observed and the relevant biopolymeric material with its relevant ligand separated from the others by segregating out a particular polymer structure (e.g. separating out a small portion of sol-gel material contained in an array). (see col. 25,

lines 40-57). The composition comprises a polymerized biological material immobilized in porous glass that undergo conformation changes when exposed to analytes, producing a detectable color change. Sol-gel refers to preparations composed of porous metal oxide glass structures. Such structures can have biological or other material entrapped within the porous structures. The phrase sol-gel matrices refers to the structures comprising the porous metal oxide glass with or without entrapped material. Metal oxide glass refers to glass material any materials made from silicates (silica based-glass), titanates, aluminates, etc. (see col. 7, lines 8-32). Since the biomolecular components of the biomolecular interactions are the same as those of the present invention, they are inherently reversibly dissociated from the other and the biomolecular interaction is bioactive. The carrier is derived from sol-gel method (see col. 7, lines 14-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al. (US 6,225,047) in view of Charych (US 6,022,748).

Hutchens teaches a method of high through put screening for a substance which modulates a biomolecular interaction comprising the steps of exposing a substrate comprising of an absorbent, i.e. an biospecific ligand for the target analyte, to a sample

and allow binding of the analyte and the ligand to take place on the substrate (chromatography column); wash with an eluant such as urea; exposing the agent to the substrate; detecting an amount of binding between the target analyte and the adsorbent by desorption spectrometry and determining whether the measured amount is different than a control amount of binding when the substrate is exposed to the target analyte under the elution condition without the agent (substance). Since Hutchens teaches washing the substrate with an eluant, it is inherent that the eluant is added and then removed. The agent can be detected directly using labels such as fluorescent moiety. (see col. 25, lines 40-45; col. 45, lines 44-65). A difference between the measured amount the control amount indicates that the agent modulates binding. (see col. 8, line 61-col. 9, line 30). The elution conditions refer to the elution characteristics to which an analyte is exposed. The sample containing the analyte can contact to the adsorbent before or after the adsorbent is affixed on the substrate. The adsorbent may be in liquid form or solid form. The adsorbent can be in dispersion, solution, suspension or water-in-oil emulsion. (see col. 19, line 1-10). The substrate is any material that can hold the adsorbent. Such materials are organic polymers, native biopolymers, bead, agarose, and cellulose of dextran. The substrate can be in the form of a probe or a sample presenting means that is inserted into a desorpsion detector. The substrate can be a strip and the absorbent can be attached to the substrate in the form of a linear array of spots, each of which can be exposed to analyte. The substrate can be glass, ceramic, electrically conducting polymers, native biopolymers, metals, films, porous and non-porous beads of crosslinked polymers. (see col. 19, lines 18-38). Thus, this enables

high through put screening of analyte. After the sample is contacted with the adsorbent resulting in the binding of the analyte to the adsorbent, the adsorbent is washed with eluant such as urea (col. 23, lines 11-15; col. 32, line 13-15). Since urea is used as an eluant and the instant specification describes that urea is a denaturant to reversibly disrupt the biomolecular interaction, disruption occurs when urea is added to the substrate after the binding of the analyte and the adsorbent. Detection is carried out using UV laser, nitrogen laser or energy from flash lamp (see col. 24, lines 25-45; col. 55, lines 36-46). Since a nitrogen laser is used, it is inherent that the signal is excited through a bifurcated optical fiber because nitrogen laser contains such a fiber. Biospecific interaction adsorbents are biospecific affinity adsorbents such as those described in col. 29, lines 45-65. Regarding claim 40, since Hutchens teaches using the nitrogen laser, the signal must be detected through the same fiber.

However, Hutchens fails to teach the biomolecular interaction is incorporated within a sol-gel substrate.

Charych has been discussed above. Charych particularly teaches using sol-gel matrices as carrier to entrap biomolecular interactions.

It would have been obvious to one of ordinary skills in the art to use the sol-gel matrix and encapsulate the biomolecular interaction as taught by Charych in the screening method of Hutchens since both teach screening test agent that modulates (inhibits or binds) the biomolecular interaction of a target analyte and a receptor/adsorbent. Since Hutches teaches that the adsorbent can be affixed to glass support and Charych teaches using a metal oxide glass carrier to entrap the biospecific

ligand (or adsorbent), one skilled in the art would have reasonable expectation of success in combining the two references. Sol-gel encapsulation not only provides an excellent way to immobilize liposomes and other biopolymer material but the optical clarity of the metal oxide gel also makes it ideal for optical sensor applications. This unique composite can easily be applied to surfaces and cast into any shape desired, allowing configuration to most any sensor platform. The robust nature of the sol-gel material converts the biopolymer material based assays into sensor materials that afford good durability, handling, portability and improve storage life while maintaining sensitivity. In addition, the metal oxide gel's porous structure and ionic surface can be tailored to provide a primary screening mechanism and preconcentrator for selective recognition and sensing of target analytes. The biolymeric/sol-gel material is a unique class of organic-inorganic composite that offers high matrix stability against microbial attack, temperature changes, and physical stress as opposed to polysaccharide and acrylate gels. (see Charych col. 6, lines 14-34).

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens and Charych as applied to claims 38-40 above, and further in view of Morrison (US 4,822,733).

Hutchens and Charych have been discussed above.

However, both references fail to teach that the signal is detected in a time gated or time resolved mode.

Morrison teaches that nitrogen laser is used to measure time-resolved fluorescence. (see col. 9, lines 51-55).

It would have been obvious to one of ordinary skills in the art to measure time-resolved signal as taught by Morrison using nitrogen laser in the combined method taught by Hutchens and Charych since Hutchens and Charych teaches using laser such as nitrogen laser to measure the signal and Morrison teaches using nitrogen laser to measure time-resolved fluorescence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
October 29, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/31/05